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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,733	10/30/2001	D. Wade Walke	LEX-0263-USA	9776

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LEXICON GENETICS INCORPORATED
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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,733

Applicant(s)

WALKE ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's Amendment filed March 18, 2004, has been entered and it is agreed that the new claims 5-18 introduce no new matter where the subject matters described by the new claims 5-18 were disclosed in the original claims 1-4 or are disclosed in the specification. No restriction requirement need be stated between the originally-claimed and the newly-claimed subject matters, and, as was the case with the original claims 1-4, the new claims 5-18 present no issues of enablement as to making, nor of indefinite description, under the first paragraph and second paragraphs of 35 U.S.C. § 112. This is because the scope of the intended subject matter is clear and the artisan can prepare both the generic expression vectors of claims 9-13 and the generic host cells of claims 14-18. Applicant's cancellation of claims 2-4 leaves claims 1 and 5-18 pending herein. The Amendment filed March 18, 2004, does not overcome rejections of record for lack of utility and for lack of enablement as to use under, respectively, 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, stated in the Office communication mailed October 16, 2003, for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 5-18 are for reasons of record rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

This is essentially the rejection of record but, in view of Applicant's Amendment filed March 18, 2004, is extended to include the new claims 5-18 because the lack of a specific utility of a claimed nucleic acid sequence perforce entails a lack of utility of recombinant expression vectors and host cells that comprise it where neither the

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vectors nor the host cells can be used to make an encoded product that has a specific utility. Applicant's arguments at pages 5-18 in the Response filed March 18, 2004, have been fully considered but are not persuasive. Applicant first suggests that a subsequent disclosure of specific substrates for a metalloprotease closely-related to that encoded by SEQ ID NO:1 herein by Chesneau et al., made of record herewith, can retroactively confer a specific utility to the nucleic acid sequences, vectors and host cells described by the pending claims. The instant specification has the same disclosure as Applicant's November 2000-filed priority document, the U.S. Provisional patent application serial No. 60/244,939, and neither the priority application nor the instant application disclose a corresponding, specific, utility that could provide the public with a useful invention commencing with the term of exclusory rights Applicant would enjoy should a patent issue in the instant application. An inventor meets the statutory requirement for utility by providing a specific benefit in currently available form and this requirement cannot be met by the subsequent discoveries of others.

While the specification and Applicant's priority document disclose the presence of polymorphisms at page 17, Applicant's argument based on a proposed forensic utility is pertinent only to the new claims 5-8 that require specific nucleotide sequences and is not considered applicable to subject matters of claims 1 and 9-18 where the claimed products have no property that might permit them to serve the alleged utility. Applicant's argument does not identify any particular degree of representation in any human population for the non-isocoding polymorphisms, thus the alleged forensic utility is indeed considered to be generic in that it is no more specific in identification of an individual than use of other polymorphism(s) anywhere else in the sequences of the human chromosomes. Applicant's alleged forensic utility of the disclosed non-isocoding polymorphisms is indistinguishable from the use of both isocoding polymorphisms in

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genes and polymorphisms in non-coding regions of genes. Insofar as the specification fails to disclose or suggest a forensic utility, e.g., at pages 1 and 8 where utilities of nucleotide sequences are discussed, it is clear that Applicant had not contemplated such an alleged utility at the time filed the instant application. An undisclosed utility cannot be considered to be a specific and substantial utility Applicant conveyed to the public at the time application was filed.

Unlike the appellate decisions that Applicant cites, the invention claimed herein is not an article of manufacture, as in *Carl Zeiss*, nor a pharmaceutical composition where a specific utility had been disclosed for the component considered by the appellate panel in *Brana*, but a "molecule", see claims 1 and 5-8, that is a heteropolymer, a linear array of four nucleotides arranged in varying sequences that, in the claimed sequences, encode a polypeptide, and it is the claimed molecule that must have a specific and substantial utility. Although Applicant believes that evidence should be gathered and cited in a rejection for lack of utility to demonstrate that an alleged utility is non-specific, insubstantial or incredible, it is clear that there is a lack of evidence in the record that the specification disclosed, at the time it was filed, either a specific or substantial utility for the claimed nucleic acid sequences. An assertion of utility must be based on some utility specific to the claimed molecule.

A claimed invention must possess a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by the claims known to the inventors at the time the application was filed as evidenced by the disclosure of the specification. No requirement for a "unique" utility is maintained in this rejection, only a requirement that a utility specific to a claimed molecule be disclosed to the public so that something may be achieved specifically with a claimed nucleic acid sequence. Applicant additionally argues that the

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specification discloses a specific *in vitro* for at least an isolated nucleic acid sequence having the nucleotide sequences of SEQ IDs NOs:1, 3, 5 and 7 in preparing nucleic acid sequence microarrays or "gene chips" and in mapping a human chromosome but these cannot be specific utilities, and are only suggestions of a generic utility, where the specification discloses no cellular, physiological, or *in vitro* uses for the expressed products of the claimed nucleic acid sequences and where any other nucleic acid sequences of similar size from a human chromosome will serve the same purpose. Where the specification discloses no biological or physiological significance for the splicing that Applicant alleges to confer a specific utility, this argument similarly has no merit. It is agreed that the threshold for utility is not high and that utility is conferred by disclosure of an "identifiable benefit" provided by a claimed invention but the specification and Applicant's argument cannot, together, demonstrate a specific, i.e., identifiable, benefit the public could be provided that is identified in the disclosure. The rejection of record is therefore sustained as to the original claim 1 and sustained as well as to new claims 5-18 the subject matters of which cannot benefit from the arguments Applicant presents in traversal of the rejection of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-18 are also rejected, essentially for reasons of record, under the first paragraph of 35 U.S.C. § 112, where the rejection of record is extended to include the new claims 5-13 in view of Applicant's Amendment filed March 18, 2004. Applicant's arguments at pages 18 and 19 in the Response filed March 18, have been fully

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considered but are not persuasive. Specifically, since the record does not show that the inventions described by claims 1 and 5-8 have a specific or substantial utility, indeed are not supported by either a specific asserted utility or a well established utility for the reasons set forth above, neither may the recombinant expression vectors and host cells of claims 9-18 that comprise such nucleic acid molecules be considered to be supported by either a specific asserted utility or a well established utility, and one skilled in the art clearly would not know how to **use** the claimed invention.

Conclusion

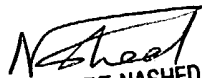
To the extent the rejection of record is extended to the new claims, Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
May 5, 2004


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER